

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

CONCEIVEX, INC.,)	
)	
Plaintiff,)	Case No.:
)	
v.)	Judge:
)	
RINOVUM WOMEN’S HEALTH, INC.,)	JURY TRIAL DEMANDED
)	
Defendant.)	

COMPLAINT FOR COPYRIGHT INFRINGEMENT

Plaintiff Conceivex, Inc. (“Conceivex”), for its Complaint against Defendant Rinovum Women’s Health, Inc. (“Rinovum”), alleges as follows:

Nature Of Action, Parties, And Jurisdiction

1. This is a civil action for copyright infringement under the Copyright Act of 1976, 17 U.S.C. §§ 101 *et seq.*
2. This Court has subject matter jurisdiction of this action under 28 U.S.C. §§ 1331, 1332, and 1338. The matter in controversy exceeds the sum of \$75,000, exclusive of interests and costs.
3. Conceivex is a Michigan corporation with its principal place of business at 4111 Andover Road, Bloomfield Hills, MI 48302-1925. Conceivex is a leader in assisting couples to overcome difficulties in conceiving. It offers the CONCEPTION KIT at-home fertility system. The U.S. Patent & Trademark Office has issued Federal Trademark Registration No. 3466195 for the mark CONCEPTION KIT. The Registration is incontestable.
4. On information and belief, defendant Rinovum Women’s Health, Inc. (“Rinovum”) is a Delaware limited liability company with its principal place of business at 300 Oxford Drive, Suite 330, Monroeville, PA 15146. Rinovum offers THE STORK OTC Home Conception Device, which it

promotes as a “device that offers a relaxed and private way of using cervical cap insemination in your own home to help with becoming pregnant.” See <http://www.storkotc.com>. Rinovum further states that THE STORK OTC Device is “a home conception device using cervical cap insemination to help with becoming pregnant in the privacy and comfort of your own home.” See <http://www.storkotc.com/how-it-works/>.

5. On information and belief, Rinovum, through its agents and representatives: has done, and is doing, business in this District; has and is engaged in acts and/or omissions within this District causing injury to Conceivex; and has and is engaged in acts and/or omissions outside of this District causing injury to Conceivex within this District. Thus, Rinovum has, and has had, minimum contacts with this District such that the Court has personal jurisdiction over Rinovum.

Copyright Infringement, 17 U.S.C. §§ 106 and 501

6. Conceivex, itself or through one or more of its predecessors-in-interest, is the author of a document entitled “Instructions for Use” for its CONCEPTION KIT at-home fertility system Conceivex. (Exh. A.) The “Instructions for Use” are included in every CONCEPTION KIT system, and include (among other things) numerous warnings intended to educate users on how to safely use the CONCEPTION KIT system.

7. The “Instructions for Use” (hereinafter, the “Work”) is an original work of authorship entitled to the full protection of the Copyright Laws, 17 U.S.C. §§ 101 *et seq.*

8. The U.S. Copyright Office has issued Copyright Registration No. TX 6-446-608 for the Work, with an effective date of September 18, 2006. (Exh. B.)

9. Rinovum has reproduced, distributed, publicly performed, publicly displayed, and/or prepared materials that are copies of the Work, that are substantially similar to the Work, and/or that are derivative of the Work.

10. Specifically, THE STORK OTC Home Conception Device includes documentation with warnings intended to educate users on how to safely use THE STORK OTC Home Conception Device. (Exh. C.) Many of the warnings in the documentation included with THE STORK OTC Home Conception Device have been copied from, or are substantially similar to, text from Conceivex's Work. For example:

Conceivex's Work ("Instructions for Use") (Exh. A)	Rinovum's Warnings (THE STORK OTC) (Exh. C)
Pregnancy may involve serious health risks for both you and your unborn child. Consult your health care professional for possible health risks before use of the Conception Kit™. [pp. 1, 6, 9]	Pregnancy may involve serious health risks for both you and your unborn child. Consult your health care professional for possible risks before use of The Stork OTC. [# 2]
Conception Kit™ components are not intended for contraceptive use. Safety and effectiveness of the Conception Kit's® Cervical Cap for contraception have not been established. [p. 6]	The Stork OTC and its components are not intended for contraceptive use. Safety and effectiveness of The Stork OTC for contraception have not been established. [# 3]
Conception Kit™ components will not protect against HIV or any other sexually transmitted diseases (STD's). [p. 6] Do not use semen from a partner who has HIV or other sexually transmitted disease (STD). [p. 18] To avoid HIV or other sexually transmitted diseases (STD's). Do not share the Conception Kit™. [p. 20]	The Stork OTC conception system will not protect against HIV or other sexually transmitted diseases. Do not use semen from a partner who has HIV or other sexually transmitted diseases. To avoid HIV or other STDs, do NOT share The Stork OTC. [# 4]
Remove the Conception Cap after 6 to 8 hours or after use overnight. Failure to remove the Conception Cap could result in blocked menstrual flow or infection. [p. 20]	Remove the cervical cap after 6 hours of wear. Do not wear longer than 6 hours. Failure to remove the cervical cap could result in complications, including obstruction of physiological discharge and menstrual flow from the uterus, pain and abrasion/ulceration and/or infection. [# 6]
If lesions, open sores, viral warts or other abnormalities are noticeable on either party, avoid sexual intercourse and consult your healthcare professional [p. 18]	If lesions, open sores, viral warts or other abnormalities are noticeable on either partner, avoid sexual intercourse and consult your healthcare professional [# 13]

Conceivex's Work ("Instructions for Use") (Exh. A)	Rinovum's Warnings (THE STORK OTC) (Exh. C)
Do not use condoms. Condoms may contain latex or spermicide, which could kill sperm and impede your opportunity to conceive. [p. 18]	Do not use regular condoms. Condoms may contain latex or spermicide which could kill sperm and impede your conception chances. [# 8]
<p>In the following situations you should consult your healthcare professional:</p> <p>If you are not sure about insertion and placement of the Conception Cap.</p> <p>If you experience any discomfort or pain while the Conception Cap is in place.</p> <p>If, at a time other than during menstruation, upon removal there is blood on the Conception Cap.</p> <p>If you are unable to remove the Conception Cap. [p. 20]</p>	<p>If you experience any of the following you should consult your healthcare professional:</p> <p>If you are not sure about insertion and placement of the cervical cap</p> <p>If you experience any pain or discomfort during this process</p> <p>If at a time other than during menstruation, upon removal there is blood on the cervical cap.</p> <p>If the withdrawal string breaks, retrieve the cervical cap manually</p> <p>If you are unable to remove the cervical cap or any component of the device, contact your healthcare provider. [# 14]</p>

11. Rinovum does not have, and has never had, any license, authorization, permission or consent from Conceivex to reproduce, distribute, publicly perform, publicly display, or prepare derivative works based, in whole or in part, on the Work.

12. Rinovum's copying of Conceivex's Work constitutes infringement under 17 U.S.C. § 501 *et seq.*, as violating the exclusive rights granted to Conceivex by 17 U.S.C. § 106.

13. Rinovum has financially profited from its infringement.

14. Rinovum has engaged in the aforesaid acts of infringement for its own commercial and financial benefit and has failed to compensate Conceivex for Rinovum's infringing acts.

15. Rinovum's acts of infringement have been willful, intentional, and purposeful in that, among other things, Rinovum had access to the Work before engaging in its unlawful acts, and had knowledge of Conceivex's copyrights therein, thus evidencing Rinovum's intentional disregard of, and indifference to, Conceivex's rights.

16. As a direct and proximate result of Rinovum's intentionally infringing conduct, Conceivex has suffered financial damage and has sustained damage to its goodwill among customers and potential customers.

17. As a direct and proximate result of Rinovum's intentional infringing conduct, Rinovum has been unjustly enriched and Conceivex is entitled to (among other things) Rinovum's profits attributable to the infringement, including an account of, and a constructive trust with respect to, such profits.

18. As a direct and proximate result of Rinovum's intentionally infringing conduct, Conceivex is entitled to its attorneys' fees and costs pursuant to 17 U.S.C. §505 and otherwise according to law.

19. Unless enjoined by this Court, Rinovum will continue its unlawful conduct and will cause Conceivex to suffer additional harm, financial and otherwise (including irreparable harm). Absent injunctive relief, Conceivex does not have an adequate remedy at law to redress the injuries that Rinovum's wrongful conduct has caused and will continue to cause.

20. In order to obtain regulatory approval of THE STORK OTC Home Conception Device, Rinovum was required (among other things): to conduct a risk/hazard analysis of the Device; to notify the Food & Drug Administration ("FDA") of the risks and hazards; and to describe how Rinovum mitigates those risks and hazards. *See* 21 U.S.C. § 360(k) and 21 C.F.R. § 807.

21. In an effort to discharge its duty to describe how Rinovum mitigates the risks and hazards associated with THE STORK OTC Home Conception Device, Rinovum submitted to the FDA the documentation with the warnings referenced in ¶ 10, above.

22. The documentation that Rinovum submitted to the FDA includes material that Rinovum copied from Conceivex's Work.

23. On information and belief, THE STORK OTC and the labeling for THE STORK OTC includes the same warnings and precautions as Rinovum's FOCUS TOUCH Conception System, which is the predicate device for THE STORCK OTC.

24. Conceivex demands a trial by jury on all issues so triable.

Prayer for Relief

WHEREFORE, Conceivex prays for the following relief against Rinovum:

- A. For a finding that Rinovum has willfully infringed Conceivex's copyrights in the Work.
- B. For Conceivex's actual damages in such amount as may be found, as recoverable under the Copyright Act or otherwise permitted by law.
- C. For an accounting of, and the imposition of a constructive trust with respect to, Rinovum's profits attributable to its infringing activities.
- D. For statutory damages, as recoverable under the Copyright Act.
- E. For preliminary and permanent injunctive relief prohibiting Rinovum, and all persons acting in concert or participation with them, including their respective agents, servants, employees, officers, successors, licensees, assigns, and distributors, from directly or indirectly infringing Conceivex's copyrights in the Work and from marketing, offering, selling, disposing of, licensing, leasing,

transferring, using, displaying, distributing, advertising, offering for sale, reproducing or having reproduced for its benefit, developing, or manufacturing any works derived or copied from the Work, or from participating or assisting in any such activity.

F. For an order requiring that Rinovum deliver to Conceivex for impoundment and/or destruction any and all originals, copies, facsimiles, or duplicates of the Work and of the infringing work in Rinovum's possession, custody, or control.

G. For an order requiring that Rinovum recall from all third parties known to Rinovum any originals, copies, facsimiles, or duplicates of any works that infringe Conceivex's copyrights in the Work and to deliver to Conceivex for destruction all such works.

H. That Rinovum be required to file with the Court and to serve on Conceivex, within 30 days after entry of an appropriate order, a report in writing under oath setting forth in detail the manner and form in which Rinovum has complied with the Court's order.

I. An award of Conceivex's attorneys' fees, costs, and disbursements in this action.

J. For prejudgment interest on any award from this action.

K. For such other, further, and different relief as the Court deems proper under the circumstances.

/s/ John Gabrielides_____

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